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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/911,903 | 07/23/2001 | Hugh J. Pasika | 07414.0025-01000 | 4264 |
| 7590 05/18/2004 | | | EXAMINER | |
| Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. Washington, DC 20005-3315 | | | LY, CHEYNE D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |
| DATE MAILED: 05/18/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/911,903 | Applicant(s) PASIKA ET AL. | |
| | Examiner Cheyne D Ly | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,19,20,29-32 and 34-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-18,21-28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/16/01, 3/24/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-6, 9-18, 21-28, and 33, nucleic acid, filed January 30, 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-6, 9-18, 21-28, and 33, nucleic acid, are examined on the merits.

OBJECTIONS

3. The title of the invention is not descriptive because the title is directed to methods, systems, and articles of manufacture while the elected invention is directed to a method, system, and computer readable medium. A new title is required that is clearly indicative of the invention to which the claims are directed.
4. The disclosure is objected to because of the following informalities: Page 10, line 10, has a blank space. Appropriate correction is required.
5. The disclosure is objected to because of the following informalities: The instant specification has two different tables, which are designated as Table 5. For example, Page 87 has Table 5 and page 91 also has Table 5. Appropriate correction is required.
6. The disclosure is objected to because of the following informalities: Page 87 contains an illustration, and page 91 contains a flow chart indicated as Table 5, which causes the instant specification to be improper as defined by the MPEP § 608.01, under 37 CFR 1.58, and page 600-59, under ILLUSTRATIONS IN THE SPECIFICATION §. It is requested that Applicant submit the above cited illustration and flow chart in the form of formal drawings in accordance with 37 CFR 1.81.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1-6 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Specific to claims 1, 3, 4, and 9, line 1, said claims recite a "A computer-implemented method", however, nowhere in the actual claim steps is the computer implementation required which causes the claims to be vague and indefinite. The claims are unclear as to which part of the claims controls the metes and bounds of said claims. Clarification of the metes and bounds is required. Claims 2, 5, 6 and 10 are rejected for being dependent from claim 1, 3, 4, or 9.

10. Claim 1 recites the limitation "the results of each algorithm" in line 5. There is insufficient antecedent basis for this limitation in the claim. It is noted lines 3-4 recite "provide a result for each algorithm". The recitation "a result" in lines 3-4 does not provide antecedent basis for the limitation of "the results" in line 5. Claims 2 and 6 are rejected for being dependent from claim 1.

11. Claim 11 recites the limitation "the results of each algorithm" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is noted lines 5-6 recite "provide a result for each algorithm". The recitation "a result" in lines 5-6 does not provide antecedent basis for the limitation of "the results" in line 7. Claims 12 and 13 are rejected for being dependent from claim 11.

CLAIM REJECTIONS - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 1-6, 9-18, 21-28, and 33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

14. Claims 1-6, 9-18, 21-28, and 33 are rejected because said claims are directed to a method, system, and computer readable medium comprising steps for inputting and analyzing nucleic acid data without any physical alteration step, which is considered to be non-statutory subject matter. "For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory." (MPEP § 2106 (IV)(B)(2) (b), part ii). Similar to the nonstatutory example above, the instant invention comprises algorithmic steps for inputting and analyzing without any physical alteration resulted from said analysis or modeling steps.

15. It is acknowledged that the instant invention comprises steps for outputting a report, which could reasonably be construed as communication signals between processes that occur entirely within a computer system. However, "such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process" (MPEP § 2106 (IV)(B)(2) (b), part ii).

16. Further, the instant invention comprises a system and computer readable medium with the means for steps for inputting and analyzing nucleic acid data without any physical alteration step outside of said system or computer readable medium resulted for the analysis, which is considered to be non-statutory subject matter.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-6, 9-18, 21-28, and 33 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Alex et al. (September 1999).

3. Alex et al. discloses a method of using a system for consensus calling by processing fluorescent trace data (page 723, Abstract etc. and column 2, lines 10-13).

4. The system of Alex et al. accepts fluorescent trace data as inputs (page 724, column 2, lines 2-11) wherein base calls are indicated by total agreement (Figure 1), as in instant claim 1, line 2.

5. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value, and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles (page 725, column 1, line 3, to page 726, column 2, line 4), as in instant claim 1, lines 3-6.

6. The method of Alex et al. comprises five network topologies wherein the algorithms are Base call, Trace shape, Gap Fraction, and Trace Peak Intensities (page 725, column 1, lines 3-18), as in instant claim 2. It is noted that the above algorithms do not have the same nomenclature as those recited in claim 2, however, the cited algorithms serve the same functions as the algorithms disclosed in the instant specification. For example, Alex et al. discloses the

Trace Shapes algorithm which takes trace information (from sequencer) as inputs, computes peak scores for each of the four traces in each sequence; and the scores are weighted by quality (threshold) and averaged (Figure 3, and page 725, column 1, lines 13-16). The algorithm of Alex et al. is directed to heterozygous alleles (page 726, column 2, lines 1-4). The disclosure of Alex et al. above is consistent with the envelope detection caller algorithm of the instant application (page 47) as recited in claim 2.

7. Ambiguous calls may also be made by setting a threshold, if more than one output exceeds the threshold (defined complexity), and then the appropriate ambiguous call is made. If only one output is above the threshold (defined complexity), the call is unambiguous (page 726, column 1, lines 4-10). Therefore, the call is determined for outputs exceeding a threshold and no calls are determined for the outputs below said threshold (predefined complexity), as in instant claim 3.

8. Further, “[t]he base calls and traces conflict and the appropriate code is listed as the consensus call...a base calls that have been erroneously inserted, the consensus show as gap, meaning no base exists (filter) (Figure 1). Trace peak are evaluated a medium shoulder is associated with zero slope (Figure 3), as in instant claim 4, claim 16, lines 5-10, claim 17, claim 26, lines 4-9, and claim 27.

9. Peaks are listed according to their respective classification scores and weak scores are determined to be irrelevant and are not used (Figure 7), as in instant claim 5.

10. “The example is extracted from fragment assemblies of a 124 kb section of *E. coli*” (page 727, column 1, lines 12-13), as in instant claims 6, 13, 15, 18, and 28.

11. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value (high level of confidence), and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles" (page 725, column 1, line 3, to page 726, column 2, line 4). Figure 8 illustrates the different strategies for each of the respective algorithms cited above, as in instant claim 9, lines 1-9, claim 10, claim 12, claim 21, lines 5-11, and claim 22.

12. Ambiguous calls may also be made by setting a threshold, if more than one output exceeds the threshold (complexity), then the appropriate ambiguous call is made. If only one output is above threshold, the call is unambiguous (levels of confidence) (page 726, column 1, lines 4-10). Base calls that have been erroneously inserted, the consensus show as gap, meaning no base exists (filter) (Figure 1), as in instant claim 9, lines 10-13, claim 21, lines 12-15, and claim 25.

13. A report captures data generated from the above algorithms which reflects the accuracy of base calls (page 727, column 2, Discussion §, lines 6-11, and Figure 10), as instant claim 9, lines 14-15, and claim 21, lines 16-17.

14. The system of Alex et al. accepts data from DNASTAR's SeqMan II (page 727, column 1, lines 12-16). The inclusion a document by Jenson HB is not being used as prior art, but, only to show the inherent characteristic of DNASTAR. Jenson HB discloses DNASTAR is a program that runs on an IBM personal computer (processor and memory) (Jenson HB, Abstract etc.), as in instant claim 11, claim 14, claim 16, lines 1-3, claim 21, lines 1-4, claim 23, lines 1-3, claim 26, lines 1-3, and claim 33, lines 1-2.

15. Further, the system of Alex et al. accepts fluorescent trace data as inputs (page 724, column 2, lines 2-11) wherein base calls are indicated by total agreement (Figure 1), as in instant claims 11, 14, and 16, line 4.

16. The method of Alex et al. comprises five network topologies (Base call, Trace shape,...all (algorithms)) wherein a consensus call with one of these networks has the highest output value (confidence level), and its corresponding base or gap is the consensus call (agreement). "In the case of heterozygote genomes, ambiguous calls pinpoint differences between alleles (page 725, column 1, line 3, to page 726, column 2, line 4), as in instant claim 11, lines 5-8, claim 14, lines 5-6, claim 23, lines 4-7, claim 24, and claim 33, lines 3-6.

CONCLUSION

17. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Art Unit: 1631

20. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly
5/11/04

Ardin H. Marschel 5/14/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER